



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: James Ronald Lawter

Serial No.: 10/601,259

Art Unit: Not Yet Assigned

Filed: June 20, 2003

Examiner: Not Yet Assigned

For: *RAPIDLY DISINTEGRATING FORMULATIONS FOR TREATING OR PREVENTING MUCOSITIS*

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Sir:

Pursuant to 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicant submits an Information Disclosure Statement, including five (5) pages of Form PTO-1449 and copies of the forty-five (45) documents cited therein.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) prior to a first Office Action on the merits. It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any required fees to Deposit Account No. 50-1868.

**U.S. Patents**

<u>Number</u>	<u>Issue Date</u>	<u>Patentee</u>	<u>Class/Subclass</u>
3,966,808	06-29-1976	Luciano	260/559
4,754,597	07-05-1988	Buxton, et al.	53/440
4,961,926	10-09-1990	Gabrilove	424/85.1
5,046,618	09-10-1991	Wood	206/532

5,082,653	01-21-1992	Pan, et al.	424/54
5,102,870	04-07-1992	Florine, et al.	514/12
5,188,825	02-23-1993	Iles, et al.	424/78.1
5,284,963	02-08-1994	Sum, et al.	552/205
5,328,902	07-12-1994	Sum, et al.	514/152
5,343,672	09-06-1994	Kearney, et al.	53/440
5,358,118	10-25-1994	Thompson, et al.	206/538
5,386,041	01-31-1995	Sum, et al.	552/205
5,401,729	03-28-1995	Sum, et al.	514/152
5,420,272	05-30-1995	Sum, et al.	544/63
5,430,162	07-04-1995	Sum, et al.	552/205
5,545,668	08-13-1996	Skubitz, et al.	514/561
5,558,880	09-24-1996	Gole, et al.	424/484
5,576,014	11-19-1996	Mizumoto, et al.	424/435
5,631,023	05-20-1997	Kearney, et al.	424/465
5,635,489	06-03-1997	Haley	514/21
5,648,093	07-15-1997	Gole, et al.	424/484
5,729,958	03-24-1998	Kearney, et al.	53/440
5,827,541	10-27-1998	Yarwood, et al.	424/489
5,837,287	11-17-1998	Yarwood, et al.	424/484
5,886,175	03-23-1999	Sum, et al.	544/63
5,945,089	08-31-1999	Libin	424/54
5,981,499	11-09-1999	Hau	514/29
6,024,981	02-15-2000	Khankari, et al.	424/464
6,025,326	02-15-2000	Steinberg, et al.	514/2
6,156,339	12-05-2000	Grother, et al.	424/450
6,221,392	04-24-2001	Khankari, et al.	424/464
6,316,027	11-13-2001	Johnson, et al.	424/464

#### Foreign Documents

<u>Number</u>	<u>Publication Date</u>	<u>Patentee</u>	<u>Country</u>
WO 99/45910	09-16-1999	Mucosal Therapeutics, Inc.	PCT
WO 01/19362	03-22-2001	Orapharma, Inc.	PCT

#### Publications

BARKER, et al., "Oral care with vancomycin paste for reduction in incidence of alpha-hemolytic streptococcal sepsis," *J Pediatr Hematol Oncol* 17(2): 151-55 (1995).

BELLM, et al., "Assessment of various topical oral formulations by bone marrow transplant recipients," *Oral Oncology* 37: 42-49 (2001).

EPSTEIN & WONG, "The efficacy of sucralfate suspension in the prevention of oral mucositis due to radiation therapy," *Int. J. Radiat. Oncol. Biol. Phys.* 28(3): 693-98 (1994).

KOROLKAVAS & BURCKHALTER, eds., Essentials of Medicinal Chemistry, John Wiley and Sons, Inc.: New York, p. 512-517 (1976).

LOPRINZI, et al., "Alleviation of cytotoxic therapy-induced normal tissue damage," *Sem. Oncol.* 22(2) Suppl. 3:95-97 (1995).

MITSCHER, et al., "Quinolone antimicrobial agents. 1. Versatile new synthesis of 1-alkyl-1,4-dihydro-4-oxo-3-quinolinecarboxylic acids," *J. Med. Chem.* 21(5):485-9 (1978).

ROTHWELL & SPEKTOR, "Palliation of radiation-related mucositis," *Special Care in Dentistry* 10(1):21-25 (1990).

SONIS, "Oral Complications in Cancer Therapy," in Principles and Practice of Oncology, vol. 2 (De Vitta et al., eds.) J.B. Lippincott Co.: Philadelphia, p. 2385-2394 (1993).

SONIS, "Oral Complications," in Gastrointestinal Complications, Lea & Febiger: Philadelphia, p. 2381-2388 (1993).


SPIJKERVET, et al., "Chlorhexidine inactivation by saliva," *Oral Surg. Oral Med. Oral Pathol.* 69(4):444-49 (1990).

VERDI, et al., "A double-blind, randomized, placebo-controlled, crossover trial of pentoxifylline for the prevention of chemotherapy-induced oral mucositis," *Oral Surg. Oral Med. Oral Pathol. Oral Radiol. Endod.* 80(1):36-42 (1995).

**Remarks**

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicant invites the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicant is of the opinion that his claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,



Patrea L. Pabst  
Reg. No. 31,284

Dated: September 4, 2003

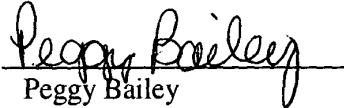
HOLLAND & KNIGHT LLP  
One Atlantic Center  
1201 West Peachtree Street, N.E.  
Suite 2000  
Atlanta, Georgia 30309-3400  
404-817-8473  
FAX 404-817-8588  
www.hklaw.com

U.S.S.N.: 10/601,259  
Filed: June 20, 2003  
INFORMATION DISCLOSURE STATEMENT

**Certificate of Mailing under 37 C.F.R. § 1.8(a)**

I hereby certify that this Information Disclosure Statement, along with any paper referred to as being attached or enclosed, is being deposited with the United States Postal Service on the date shown below with sufficient postage as first-class mail in an envelope addressed to the Assistant Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Peggy Bailey

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		Application Number	10/601,259
		Filing Date	June 20, 2003
		First Named Inventor	James Ronald Lawter
		Group Art Unit	
		Examiner Name	
Sheet 1 of 5	Attorney Docket Number	ORA 104	

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	US Patent Document		Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
		3,966,808		Luciano	06-29-1976	
		4,754,597		Buxton, et al.	07-05-1988	
		4,961,926		Gabrilove	10-09-1990	
		5,046,618		Wood	09-10-1991	
		5,082,653		Pan, et al.	01-21-1992	
		5,102,870		Florine, et al.	04-07-1992	
		5,188,825		Iles, et al.	02-23-1993	
		5,284,963		Sum, et al.	02-08-1994	
		5,328,902		Sum, et al.	07-12-1994	
		5,343,672		Kearney, et al.	09-06-1994	
		5,358,118		Thompson, et al.	10-25-1994	
		5,386,041		Sum, et al.	01-31-1995	
		5,401,729		Sum, et al.	03-28-1995	
		5,420,272		Sum, et al.	05-30-1995	
		5,430,162		Sum, et al.	07-04-1995	

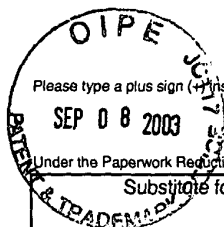
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Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>3</sup>
		Office. <sup>4</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
		PCT	WO 99/45910		Mucosal Therapeutics, Inc.	09-16-1999		
		PCT	WO 01/19362		Orapharma, Inc.	03-22-2001		

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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

<sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant to place a check mark here if English language Translation is attached.

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Application Number	10/601,259
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First Named Inventor	James Ronald Lawter
Group Art Unit	
Examiner Name	
Attorney Docket Number	ORA 104

Sheet	2	of	5
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		5,576,014		Mizumoto, et al.	11-19-1996	
		5,631,023		Kearney, et al.	05-20-1997	
		5,635,489		Haley	06-03-1997	
		5,648,093		Gole, et al.	07-15-1997	
		5,729,958		Kearney, et al.	03-24-1998	
		5,827,541		Yarwood, et al.	10-27-1998	
		5,837,287		Yarwood, et al.	11-17-1998	
		5,886,175		Sum, et al.	03-23-1999	
		5,945,089		Libin	08-31-1999	
		5,981,499		Hau	11-09-1999	
		6,024,981		Khankari, et al.	02-15-2000	
		6,025,326		Steinberg, et al.	02-15-2000	
		6,156,339		Grother, et al.	12-05-2000	

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		Office. <sup>4</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				

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Applicati n Number	Applicant Name	Applicant Address	Applicant City	Applicant State	Applicant Zip	Applicant Phone	Applicant Email	Applicant Fax	Applicant Website	Applicant Notes
1	John Doe	123 Main St	Anytown	CA	90210	(555) 123-4567	john.doe@example.com	(555) 123-4567	http://www.johndoe.com	Interested in...
2	Jane Smith	456 Elm St	Anytown	CA	90210	(555) 234-5678	jane.smith@example.com	(555) 234-5678	http://www.janesmith.com	Interested in...
3	Bob Johnson	789 Oak St	Anytown	CA	90210	(555) 345-6789	bob.johnson@example.com	(555) 345-6789	http://www.bobjohnson.com	Interested in...
4	Alice Brown	101 Pine St	Anytown	CA	90210	(555) 456-7890	alice.brown@example.com	(555) 456-7890	http://www.alicebrown.com	Interested in...
5	Charlie Davis	202 Pine St	Anytown	CA	90210	(555) 567-8901	charlie.davis@example.com	(555) 567-8901	http://www.charliedavis.com	Interested in...
6	Diana Evans	303 Pine St	Anytown	CA	90210	(555) 678-9012	diana.evans@example.com	(555) 678-9012	http://www.dianaevans.com	Interested in...
7	Frank Green	404 Pine St	Anytown	CA	90210	(555) 789-0123	frank.green@example.com	(555) 789-0123	http://www.frankgreen.com	Interested in...
8	Grace Hill	505 Pine St	Anytown	CA	90210	(555) 890-1234	grace.hill@example.com	(555) 890-1234	http://www.gracehill.com	Interested in...
9	Henry King	606 Pine St	Anytown	CA	90210	(555) 901-2345	henry.king@example.com	(555) 901-2345	http://www.henryking.com	Interested in...
10	Ivy Lee	707 Pine St	Anytown	CA	90210	(555) 012-3456	ivy.lee@example.com	(555) 012-3456	http://www.ivylee.com	Interested in...
11	Jack Miller	808 Pine St	Anytown	CA	90210	(555) 123-4567	jack.miller@example.com	(555) 123-4567	http://www.jackmiller.com	Interested in...
12	Karen Wilson	909 Pine St	Anytown	CA	90210	(555) 234-5678	karen.wilson@example.com	(555) 234-5678	http://www.karenwilson.com	Interested in...
13	Leo White	1010 Pine St	Anytown	CA	90210	(555) 345-6789	leo.white@example.com	(555) 345-6789	http://www.leowhite.com	Interested in...
14	Mia Black	1111 Pine St	Anytown	CA	90210	(555) 456-7890	mia.black@example.com	(555) 456-7890	http://www.miablack.com	Interested in...
15	Noah Gray	1212 Pine St	Anytown	CA	90210	(555) 567-8901	noah.gray@example.com	(555) 567-8901	http://www.noahgray.com	Interested in...
16	Olivia Blue	1313 Pine St	Anytown	CA	90210	(555) 678-9012	olivia.blue@example.com	(555) 678-9012	http://www.oliviablue.com	Interested in...
17	Peter Red	1414 Pine St	Anytown	CA	90210	(555) 789-0123	peter.red@example.com	(555) 789-0123	http://www.peterred.com	Interested in...
18	Quinn Yellow	1515 Pine St	Anytown	CA	90210	(555) 890-1234	quinn.yellow@example.com	(555) 890-1234	http://www.quinnyellow.com	Interested in...
19	Rachel Purple	1616 Pine St	Anytown	CA	90210	(555) 901-2345	rachel.purple@example.com	(555) 901-2345	http://www.rachelpurple.com	Interested in...
20	Sam Brown	1717 Pine St	Anytown	CA	90210	(555) 012-3456	sam.brown@example.com	(555) 012-3456	http://www.sambrown.com	Interested in...
21	Tina Green	1818 Pine St	Anytown	CA	90210	(555) 123-4567	tina.green@example.com	(555) 123-4567	http://www.tinagreen.com	Interested in...
22	Uma White	1919 Pine St	Anytown	CA	90210	(555) 234-5678	uma.white@example.com	(555) 234-5678	http://www.umawhite.com	Interested in...
23	Victor Black	2020 Pine St	Anytown	CA	90210	(555) 345-6789	victor.black@example.com	(555) 345-6789	http://www.victorblack.com	Interested in...
24	Wendy Gray	2121 Pine St	Anytown	CA	90210	(555) 456-7890	wendy.gray@example.com	(555) 456-7890	http://www.wendygray.com	Interested in...
25	Xavier Blue	2222 Pine St	Anytown	CA	90210	(555) 567-8901	xavier.blue@example.com	(555) 567-8901	http://www.xavierblue.com	Interested in...
26	Yara Red	2323 Pine St	Anytown	CA	90210	(555) 678-9012	yara.red@example.com	(555) 678-9012	http://www.yarared.com	Interested in...
27	Zoe Yellow	2424 Pine St	Anytown	CA	90210	(555) 789-0123	zoe.yellow@example.com	(555) 789-0123	http://www.zoeyellow.com	Interested in...
28	Adam Purple	2525 Pine St	Anytown	CA	90210	(555) 890-1234	adam.purple@example.com	(555) 890-1234	http://www.adampurple.com	Interested in...
29	Bella Brown	2626 Pine St	Anytown	CA	90210	(555) 901-2345	bella.brown@example.com	(555) 901-2345	http://www.bellabrown.com	Interested in...
30	Chris Green	2727 Pine St	Anytown	CA	90210	(555) 012-3456	chris.green@example.com	(555) 012-3456	http://www.chrisgreen.com	Interested in...
31	Diana White	2828 Pine St	Anytown	CA						

**10/601,259**

Filing Date

June 20, 2003

**First Named Inventor**

James Ronald Lawter

### Group Art Unit

**Examiner Name**

Attorney Docket Number

ORA 104

Sheet

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of

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## U.S. PATENT DOCUMENTS

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## FOREIGN PATENT DOCUMENTS

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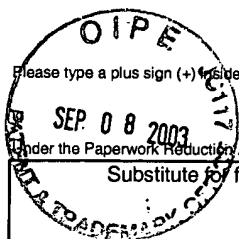
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First Named Inventor	James Ronald Lawter
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Attorney Docket Number	ORA 104

Sheet 4 of 5

### OTHER ART -- NON PATENT LITERATURE DOCUMENTS

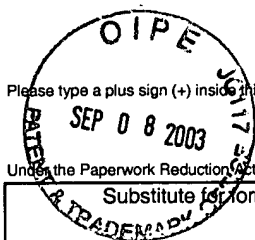
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	/	BARKER, et al., "Oral care with vancomycin paste for reduction in incidence of alpha-hemolytic streptococcal sepsis," <i>J Pediatr Hematol Oncol</i> 17(2): 151-55 (1995).	
	/	BELLM, et al., "Assessment of various topical oral formulations by bone marrow transplant recipients," <i>Oral Oncology</i> 37: 42-49 (2001).	
	/	EPSTEIN & WONG, "The efficacy of sucralfate suspension in the prevention of oral mucositis due to radiation therapy," <i>Int. J. Radiat. Oncol. Biol. Phys.</i> 28(3): 693-98 (1994).	
	/	KOROLKAVAS & BURCKHALTER, eds., <u>Essentials of Medicinal Chemistry</u> , John Wiley and Sons, Inc.: New York, p. 512-517 (1976).	
	/	LOPRINZI, et al., "Alleviation of cytotoxic therapy-induced normal tissue damage," <i>Sem. Oncol.</i> 22(2) Suppl. 3:95-97 (1995).	
	/	MITSCHER, et al., "Quinolone antimicrobial agents. 1. Versatile new synthesis of 1-alkyl-1,4-dihydro-4-oxo-3-quinolinecarboxylic acids," <i>J. Med. Chem.</i> 21(5):485-9 (1978).	
	/	ROTHWELL & SPEKTOR, "Palliation of radiation-related mucositis," <i>Special Care in Dentistry</i> 10(1):21-25 (1990).	
	/	SONIS, "Oral Complications in Cancer Therapy," in <u>Principles and Practice of Oncology</u> , vol. 2 (De Vitta et al., eds.) J.B. Lippincott Co.: Philadelphia, p. 2385-2394 (1993).	
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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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### Complete if Known

Application Number	10/601,259
Filing Date	June 20, 2003
First Named Inventor	James Ronald Lawter
Group Art Unit	
Examiner Name	
Attorney Docket Number	ORA 104

Sheet

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of

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### OTHER ART -- NON PATENT LITERATURE DOCUMENTS

Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		VERDI, et al., "A double-blind, randomized, placebo-controlled, crossover trial of pentoxifylline for the prevention of chemotherapy-induced oral mucositis," <i>Oral Surg. Oral Med. Oral Pathol. Oral Radiol. Endod.</i> 80(1):36-42 (1995).	

Examiner's  
Signature

Date Considered

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